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OBJECTIVES: 1) To identify antidiabetic products approved with a Patient-Reported Outcome (PRO) labeling claim in Europe and the USA, and 2) to list the differences found in Europe versus the USA in terms of products and labeling. **METHODS:** The search was performed on the FDA- and EMA-approved medicinal product labels (from 1995 to August 2012 inclusive). The review was conducted through a systematic manual review of antidiabetic product labelings. **RESULTS:** A total of 96 antidiabetic products were retrieved: 53 approved by the EMA, 43 by the FDA (generics excluded). Only two products with a PRO labeling claim were found in Europe (i.e., Insulin Glulisin and Exenatid), and none in the USA. PROs identified in both claims were self-monitored blood glucose (SMBG) profiles and were used as secondary endpoints. Although Insulin Glulisin and Exenatid were also approved by the FDA (on the same studies used in Europe) their US label did not mention any results based on SMBG profiles. Reasons for not including them in the label were not given in the corresponding medical reviews. However, the analysis of other products' reviews, such as Insulin Aspart or Liraglutide, showed a reluctance from reviewers to include results based on SMBG profiles in the labels. Reviewers questioned the validity of the glucose profiles based on self-collected readings because of compliance issues and of a lower degree of accuracy of values obtained from glucometers versus lab measures in a clinic. Although measured in some cases, other PROs, such as quality of life or treatment satisfaction, were never considered for inclusion in labeling with any reasons given. **CONCLUSIONS:** Our review showed that Patient-Reported Outcomes are rarely included in antidiabetic product labels in Europe and in the US. Other than discussions on the validity of self-monitored blood glucose profiles, reasons for such non-inclusion were not provided.

PDB77

A CROSS SECTIONAL ASSESSMENT OF KNOWLEDGE TOWARDS DIABETES MELLITUS AMONG URBAN POOR POPULATION OF PENANG, MALAYSIA

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OBJECTIVES: To assess diabetes related knowledge among urban poor population of Tunku village, Jelutong, Penang, Malaysia. **METHODS:** A questionnaire based, cross-sectional observational study was carried out. All residence of the area (age 18 and above) were targeted. The study was conducted from September to November 2012. Descriptive statistics were applied to summarize the data. All analyses were performed by using Statistical Package for Social Sciences (SPSS) software version 17. **RESULTS:** A total of 104 residents agreed to participate in the study. The cohort was dominated by females (n=70, 67.3%) and ethnic group of Malay (n=71, 68.3%) with mean age of 56.9±13.4 years. More than half (n=61, 58.7%) of the respondents were considered as low income earners as the monthly household income was less than Ringgit Malaysia 1000. Ninety one (87.5%) knew the definition of diabetes whereas (n=77, 74%) had knowledge about the normal glucose level in the body). Eight six (82.7%) had the knowledge about the complications associated with diabetes. Majority of them believed that regular exercise can control diabetes, whereas only 25 (24%) believed that diet modification can help in managing the diabetes. Twenty one (20.2%) stated that diabetes is a disease of old age. The mean diabetes knowledge score was 6.92±2.027 out of 10. **CONCLUSIONS:** The study revealed that the respondent had adequate diabetes related knowledge. However, certain diabetes related attributes were lacking in the population. It is advisable that efforts should be made to educate the residents of the urban poor areas for adequate management of diabetes.

PDB78

THE IMPACT OF MEMORY PROBLEMS ON DIABETES TREATMENT IN CHINA

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OBJECTIVES: The impact of memory problems (MPs) on patient insulin taking behavior, functioning, well-being and diabetes management is not well understood. The purpose of this study was to examine these impacts in China, the country with the largest diabetes population in the world. **METHODS:** MPs were defined as: unintentionally forgetting (UF) to take insulin, questioning whether or not insulin had been taken (QT), or questioning how much insulin was taken (QD). A web-based survey examining circumstances leading to the MP, corrective actions taken, impact on health well-being and diabetes management was conducted. **RESULTS:** A total of 354 respondents (217 or 61.3% Type 1, 137 or 38.7% Type 2) completed the survey, 59% male, mean age of 43.2 (±13.4, 25-70) and mean age of diabetes onset of 36.9 (±12.0, 2-65). The prevalence of MPs was high, with 74.6% forgetting, 83.1% questioning whether taken and 65.8% questioning how much insulin taken in the past month. MPs occurred most frequently at work and the major reasons for the MP were being tired or busy. Depending upon MP type, between 16.2% (QD) – 20.5% (UF) of respondents skipped their insulin dose and waited for next scheduled dose when experiencing a MP and then required between 4.9 (QD)–10.1 (UF) hours to return to a normal blood glucose range. Patients conducted between 1.6 (QT/QD) –4.6 (UF) extra BG monitoring tests and reported a moderate negative impact on their physical, emotional and functioning as well as their ability to function at work. Further, between 16.2% (QT) and 40.9% (UF) visited their health care provider as a result of a MP. Economic implications include cost of additional BG monitoring strips, lost work productivity and health care resource utilization. **CONCLUSIONS:** These findings suggest that MPs in China carry financial burden, impact patients functioning and well-being and may be serious obstacles to optimal diabetes control.

PDB79

INSULIN ADMINISTRATION AND THE IMPACTS OF FORGETTING A DOSE FOR PATIENTS

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OBJECTIVES: To qualitatively examine issues regarding unintentional dosing irregularities due to memory issues which may impact insulin taking behavior in people with diabetes. **METHODS:** Seven focus groups and eight individual interviews were held (Canada, Germany, China). Respondents were recruited who had experienced at least two instances in the previous three months of forgetting the insulin dose, time/amount taken, or being unsure if they took their insulin. Transcripts were coded thematically, based on grounded theoretical approach. **RESULTS:** Sixty-four people participated: mean age 50.1 (range 18 to 72), (34% type 1, 66% type 2). Analysis generated 6 domains: behaviors forgotten, reasons for forgetting, how they became aware that they had forgotten their insulin, consequences of forgetting, corrective actions, and the emotional impact of forgetting insulin. Respondents reported forgetting both bolus and basal insulin doses and often felt uncertain about if they administered their insulin dose, the dose amount or time taken. Major reasons for these memory issues were: forgetting due to disruptions in their daily routine, distraction by social events, minor interruptions, and being generally busy. They became aware they forgot due to their own reminder systems as well as symptoms of hyperglycemia and blood glucose testing. People employ a wide variety of strategies and corrective actions when they think they have forgotten and often monitor their blood glucose more frequently following dosing irregularities. Further, patients often question as to whether or not they took their insulin with greater frequency than times when they actually forgot and worry about the impact of these behaviors on maintaining stable blood glucose control. **CONCLUSIONS:** Unintentional memory issues does impact insulin taking behavior , leads to dosing irregularities and contributes to patient uncertainty and worry about their diabetes management. Insulin strategies that assist patients in managing memory related dosing issues may reduce treatment costs, improve adherence and treatment outcomes.

PDB80

RELATIONSHIPS AMONG SYMPTOMATIC HYPOGLYCEMIA, PATIENT-REPORTED FEAR OF HYPOGLYCEMIA AND HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN TYPE-2 DIABETES MELLITUS (T2DM) PATIENTS

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OBJECTIVES: Hypoglycemia symptoms are associated with a high level of fear. This study examined the relationships among symptomatic hypoglycemia, fear of hypoglycemia, and HRQOL, and focused on whether fear of hypoglycemia is independently associated with lower HRQOL. **METHODS:** Data were collected from mail surveys and enrollment information from a sample of adult commercial health plan enrollees (n=813) with indentified type-2 diabetes during a 12-month period. Patient's HRQOL was evaluated by the EuroQol (EQ)-5D scale and SF-12 scale, and the hypoglycemia fear scale (HFS) was used to assess fear of hypoglycemia. We specified two ordinary least square (OLS) models of HRQOL, controlling for demographics and illness characteristics. We compared the regression coefficients and statistical inferences from two OLS models: Model 1 included only one variable of hypoglycemia symptoms; Model 2 included both hypoglycemia symptoms and HFS score. **RESULTS:** Model 1: The hypoglycemia symptoms alone were associated with worse HRQOL as measured by SF-12 mental component summary (MCS) and physical component summary (PCS) scores and EQ-5D utility score (all p-values <0.05). Model 2: The variable of hypoglycemia symptoms was significantly associated only with SF-12 MCS score. In contrast, the HFS total score was significantly associated with all three scores of HRQOL. The survey analysis also found that the symptoms of hypoglycemia, socioeconomic factors (e.g., Hispanic ethnicity), and longer diabetes duration were associated with higher level of hypoglycemia fear, whereas higher income level, white race, and treatment without either sulfonylurea or insulin were associated with lower hypoglycemia fear (all p-values <0.05). **CONCLUSIONS:** The fear and the experience of symptomatic hypoglycemia were both independently associated with lower HRQOL (overall health status, mental and physical health). Interventions (e.g., patient education programs) can be designed to address the fear of hypoglycemia. Choosing a therapy with a lower propensity for hypoglycemia may also positively impact QOL.

DIABETES/ENDOCRINE DISORDERS – Health Care Use & Policy Studies

PDB81

THE ROLE OF QUANTITATIVE SENSORY TESTING IN ASYMPTOMATIC DIABETIC NEUROPATHY AND ITS RELATIONSHIP WITH HBA1C

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OBJECTIVES: Patients' with diabetic neuropathy may or may not show symptoms. If its progression is not stopped at the earliest, it may lead to foot ulceration and amputation. This study was conducted to assess the role of Quantitative Sensory Testing (QST) in detection of diabetic neuropathy. Glycated hemoglobin (HbA1c) and age are two of the major risk factors for diabetic neuropathy. So, relationship of thermal thresholds was seen with HbA1c as well as age. **METHODS:** This was a retrospective observational study conducted on